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Letters from corneal surgeons



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May 7, 2001

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**Office of the Commissioner
Food and Drug Administration
5630 Fishers Lane
Rockville, MD 20852**

Dear Sirs:

Last year, calendar 2000, I performed 25 corneal transplants. All of these procedures were performed in an outpatient surgery center.

Sincerely,

**Charles Bouchard, M.D.
Director, Cornea Service**

Devers Eye Institute

Education, Research, Consultation.

1040 NW 22nd Avenue, Suite 200
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(503) 413-8202 1-800-768-2642
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Office of the Commissioner
Food and Drug Administration
5630 Fishers Lane
Rockville, MD 20852

May 4, 2001

RE: Corneal Transplantation as an Out Patient Procedure

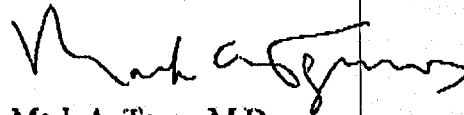
Dear Sir/Madam:

It has come to my attention that the FDA believes that the procedure of corneal transplantation surgery requires an inpatient stay in the hospital.

This is to inform you that I performed over 70 corneal transplants last year, and not a single surgery was done on an inpatient basis. Nearly all patients had only a 4 to 5 hour stay in the outpatient surgery suite before returning home after surgery, with each patient being seen in my office the next morning for their first follow-up visit. The few patients that did stay overnight after corneal transplantation surgery did so for other systemic illness complaints.

If you have any questions on this issue, please do not hesitate to contact me.

Sincerely,



Mark A. Terry, M.D.
Director, Corneal Services
Devers Eye Institute

Cc: Carrie Kovar
Barbara Crowe
Patricia Aiken-O'Neill

*Cornea, Anterior Segment &
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Joel Sugar, MD
Professor
Director, Corneal Service

April 19, 2001

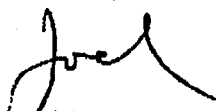
Barbara Crow, Chair
EBAA
1010 Northwest 22nd Ave.
Portland, Oregon 97210

Dear Barbara:

After reviewing the FDA "Proposed New Rules for Good Tissue Practice", it is evident that they misinterpret the indications for repeat keratoplasty. Primary donor failure is indeed an extremely uncommon reason for repeat corneal transplants. The majority of repeat transplants are done because of rejection failures, endothelial failure, or recurrence of disease in the transplant. Present tissue practices have protected our patients so that the need to repeat corneal transplant because of primary donor failure accounts for well below 1% of corneal transplants. I hope that in the new wording that you propose for changes in the FDA guidelines this point is emphasized.

For our eye bank (MEBTC) for fiscal year 200, there were 5 primary donor failures in 2795 grafts or 0.18%.

Sincerely,



Joel Sugar, MD
Professor

JS/rj

Cc: Pat Aiken-O'Neill